

This is an official **CDC HEALTH UPDATE**

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Sanofi Pasteur Monovalent 2009 (H1N1) Influenza Vaccine in Pre-Filled Syringes — Shortened Shelf Life of Certain Lots

Summary

Sanofi Pasteur has notified CDC and FDA that some lots of monovalent 2009 (H1N1) influenza vaccine in prefilled syringes will have a shorter expiration period than indicated on the label. The lots of Sanofi Pasteur monovalent 2009 H1N1 influenza vaccine in prefilled syringes should be used by February 15, 2010, as indicated in the table below regardless of the expiration imprinted on the package. This is to ensure that the vaccine is used while it remains within its potency specification. There are no safety concerns with these lots of 2009 H1N1 vaccine. People who received vaccine from the lots listed below with shortened shelf life do not need to take any action.

Background

As part of its quality assurance program, Sanofi Pasteur performs routine, ongoing stability testing of the vaccine after it has been shipped to providers. Stability testing means measuring the strength of a vaccine over time.

The 50 lots subject to this change in expiration date include approximately 12 million doses. These lots were shipped to providers between November 2009 and January 2010. Although these lots remain potent, they are losing their potency more rapidly than expected, and therefore the shelf life is being shortened. While **most of the doses from these lots are believed to have already been administered**, there are almost certainly some doses that have not yet been used.

The change in expiration date described here is specific to the 50 lots of Sanofi Pasteur 2009 H1N1 influenza vaccine in pre-filled syringes listed below. However, a related recall (See <http://www2a.cdc.gov/HAN/ArchiveSys/ViewMsgV.asp?AlertNum=00306>) was conducted recently, which involved lots from Sanofi Pasteur's 2009 H1N1 vaccine in 0.25 mL and 0.5 mL pre-filled syringes. These actions do not affect Sanofi Pasteur's 2009 H1N1 vaccine in multi-dose vials.

Sanofi Pasteur will send a notification to providers who received doses from any of the 50 lots of vaccine described below.

Lot Information

These lots should be used by February 15, 2010, as indicated in the table below regardless of the expiration date imprinted on the package.

All pre-filled syringes that have not been used by February 15, 2010 should be discarded in an appropriate manner, or you may return the product for destruction to Sanofi Pasteur Inc., c/o Capital Returns at 6101 N. 64th Street, Milwaukee, WI 53218

**Influenza A (H1N1) 2009 Monovalent Vaccine in Pre-Filled Syringes
Expiration Date Change**

| Product Code (NDC) | Description | Lot Number | Labeled Expiration Date | Re-Assigned Expiration Date |
|-------------------------------|-----------------------------------|-----------------------|------------------------------------|--|
| 49281-650-25 | 0.25mL syringes in 10-packs | UT014AA | March 4, 2011 | February 15, 2010 |
| | | UT014BA | March 4, 2011 | February 15, 2010 |
| | | UT014CA | March 4, 2011 | February 15, 2010 |
| | | UT014DA | March 4, 2011 | February 15, 2010 |
| | | UT014FA | March 27, 2011 | February 15, 2010 |
| | | UT014EA | March 25, 2011 | February 15, 2010 |
| | | UT029DA | April 7, 2011 | February 15, 2010 |
| | | UT029BA | April 6, 2011 | February 15, 2010 |
| | | UT029CA | April 6, 2011 | February 15, 2010 |
| | | UT029EA | April 8, 2011 | February 15, 2010 |
| | | UT030EA | April 10, 2011 | February 15, 2010 |
| | | UT030FA | April 11, 2011 | February 15, 2010 |
| | | UT033CA | April 12, 2011 | February 15, 2010 |
| | | UT033DA | April 12, 2011 | February 15, 2010 |

| Product Code (NDC) | Description | Lot Number | Labeled Expiration Date | Re-Assigned Expiration Date |
|-------------------------------|----------------------------------|-----------------------|------------------------------------|--|
| 49281-650-50 | 0.5mL syringes in 10-packs | UP033CA | April 16, 2011 | February 15, 2010 |
| | | UP036CA | April 19, 2011 | February 15, 2010 |
| | | UP034BB | April 22, 2011 | February 15, 2010 |
| | | UP036EA | May 3, 2011 | February 15, 2010 |
| | | UP037CA | April 30, 2011 | February 15, 2010 |
| | | UP037DA | May 2, 2011 | February 15, 2010 |
| | | UP048CA | May 6, 2011 | February 15, 2010 |
| | | UP040CA | May 4, 2011 | February 15, 2010 |
| | | UP048DA | May 9, 2011 | February 15, 2010 |
| | | UP049FA | May 16, 2011 | February 15, 2010 |
| | | UP049CA | May 11, 2011 | February 15, 2010 |
| | | UP049DA | May 13, 2011 | February 15, 2010 |
| | | UP035BA | April 15, 2011 | February 15, 2010 |
| | | UP059DA | May 16, 2011 | February 15, 2010 |
| | | UP060CA | May 17, 2011 | February 15, 2010 |
| | | UP060DA | May 19, 2011 | February 15, 2010 |
| | | UT047BA | May 11, 2011 | February 15, 2010 |
| | | UP033AB | April 9, 2011 | February 15, 2010 |
| | | UP041BA | April 30, 2011 | February 15, 2010 |
| | | UT041AA | April 29, 2011 | February 15, 2010 |
| | | UT034AA | April 19, 2011 | February 15, 2010 |
| | | UT045BA | May 5, 2011 | February 15, 2010 |
| | | UP061DA | May 21, 2011 | February 15, 2010 |
| | | UP061FA | May 23, 2011 | February 15, 2010 |
| | | UP035AA | April 12, 2011 | February 15, 2010 |
| | | UT048BA | May 12, 2011 | February 15, 2010 |
| | | UT058BA | May 16, 2011 | February 15, 2010 |
| | | UT059AA | May 18, 2011 | February 15, 2010 |
| | | UT058AA | May 14, 2011 | February 15, 2010 |
| | | UT061GA | May 24, 2011 | February 15, 2010 |
| | | UP045EA | June 9, 2011 | February 15, 2010 |
| 49281-650-90 | 0.5mL syringes in 25-packs | UT036DA | April 26, 2011 | February 15, 2010 |
| | | UT040BA | April 28, 2011 | February 15, 2010 |
| | | UT047AA | May 9, 2011 | February 15, 2010 |
| | | UT046BA | May 9, 2011 | February 15, 2010 |
| | | UT046AA | May 4, 2011 | February 15, 2010 |

For More Information:

- CDC's toll-free information line, 800-CDC-INFO (800-232-4636) TTY: (888) 232-6348, is available 24 hours a day, every day.

- For other inquiries, please contact Sanofi Pasteur Customer Services: 1-800-VACCINE (1-800-822-2463) or visit www.vaccineshoppe.com

Categories of Health Alert Messages:

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|------------------------|--|
| Health Alert | Conveys the highest level of importance; warrants immediate action or attention. |
| Health Advisory | Provides important information for a specific incident or situation; may not require immediate action. |
| Health Update | Provides updated information regarding an incident or situation; unlikely to require immediate action. |

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